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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,017	02/14/2002	Ishay Ostfeld	OSTFELD1	5626

7590

04/05/2004

BROWDY AND NEIMARK, P.L.L.C.  
624 Ninth Street, N.W.  
Washington, DC 20001

EXAMINER
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KONTOS, LINA R

ART UNIT	PAPER NUMBER
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3763

*8*

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/074,017

Applicant(s)

OSTFELD ET AL.

Examiner

Lina Kontos

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 22, 23, 32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-21, 25-28, 30, 31 and 34 is/are rejected.
- 7) ☒ Claim(s) 13, 24 and 29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1.

Claims 1-3,8-11,18,34 are rejected under 35 U.S.C. 102(b) as being anticipated by Coulter.

Coulter teaches a catheter system with one embodiment teaching an interior cover (5) for a cannula (4) and another embodiment teaches an external cover (15) for a cannula (14). The cover is removed after the device has been inserted in the patient.

2.

Claims 1,2,4,8-10,12,15,16,31,34 are rejected under 35 U.S.C. 102(b) as being anticipated by Chin.

Chin teaches a cover for a medical device such as a stent (column 4, line 45) wherein the cover has a row of perforations allowing for easy removal from the device after the system has been inserted into the patient. The perforations on the cover create a rough surface.

3.

Claim 19 is rejected under 35 U.S.C. 102(e) as being anticipated by Holman et al.

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Holman et al. teaches a cover for a stent that is helically wound over the device and may be used by itself or as an inner or outer sleeve. [0133] The helical cover is removed by unwrapping the strip. [0141]

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4.

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coulter in view of another embodiment of Coulter.

Coulter teaches two separate embodiments, one having a cover on the interior of the medical device and the other a cover on the exterior of the device. In both embodiments, the cover is removed after the device is inserted in the body.

It would have been obvious to one skilled in the art at the time of the invention to incorporate the use of both covers at the same time in order to keep all surfaces of the device sterile.

5.

Claims 17,30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coulter in view of Maloney et al.

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Coutler, as described above, teaches a cover for a medical device that is removed after the device is inserted into the patient, but fails to teach a blade that splits the cover in order to remove it from the surface of the device.

Maloney et al. teaches a slitter comprising a blade used to slit an introducer for removal from a catheter.

It would have been obvious to one skilled in the art at the time of the invention to incorporate this slitter for removal means of the protective cover for the catheter system instead of having to manufacture a cover with a preformed slit.

6.

Claims 14,20,21,25,26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coulter in view of Holman et al.

Coutler, as described above, teaches a cover for a medical device that is removed after the device is inserted into the patient, but fails to teach a ring at the distal end of the shaft.

Holman et al., as described above teaches a cover for a stent, and further teaches a ring (120) as the distal end of the shaft. [0113]

It would have been obvious to one skilled in the art at the time of the invention to provide such a device in order to prevent material from entering between the cover and the surface. That the cover is impenetrable to water and microorganisms further protects the sterility of the device

7.

Claims 27,28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coulter in view of Wepsic.

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Coutler, as described above, teaches a cover for a medical device that is removed after the device is inserted into the patient, but fails to teach the cover storing and releasing a substance,

Wepsic teaches an inner cover (11) for a catheter manufactured from rubber. The inner cover is impermeable (column 1, line 58) and contains an antibacterial substance (column 1, line 62) that is delivered to the body through the permeable outer layer of the catheter. The inner cover has grooves (13-18) that provide the surface with a rough quality.

It would have been obvious to one skilled in the art at the time of the invention to have the cover store and release a substance in order to treat the area of the patient where the device is to be employed.

### ***Response to Arguments***

**8.**

Applicant's arguments with respect to claims 1-18,21,24-27,30,31 have been considered but are moot in view of the new ground(s) of rejection.

**9.**

The requirement for restriction withdrawing claims 22 and 23 from consideration is maintained by Examiner as these claims pertain the method of manufacturing the cover. Claim 28 has been considered in the action.

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## **Conclusion**

**10.**

Claims 13,24,29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

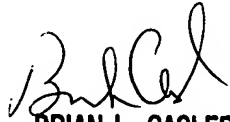
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lina Kontos whose telephone number is (703) 306-4207. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LRK

  
**BRIAN L. CASLER**  
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